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<p>(21) International Application Number: <b>PCT/US97/18168</b></p> <p>(22) International Filing Date: <b>8 October 1997 (08.10.97)</b></p> <p>(30) Priority Data:  <b>08/801,752      18 February 1997 (18.02.97)      US</b></p> <p>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application  <b>US      08/801,752 (CIP)</b>  <b>Filed on      18 February 1997 (18.02.97)</b></p> <p>(71) Applicants (for all designated States except US): <b>MEDICAL CREATIVE TECHNOLOGIES, INC. [US/US]; 2950-N Advance Lane, Colmar, PA 18915 (US). DEXTERITY INCORPORATED [US/US]; Building 16, Suite 220, 1787 Sentery Parkway West, Blue Bell, PA 19422 (US).</b></p> <p>(72) Inventors; and  (75) Inventors/Applicants (for US only): <b>CROOK, Berwyn, M. [US/US]; 921 Queens Drive, Yardley, PA 19067 (US). RAMBO, Robert, D. [US/US]; 702 Simmons Road, Sellersville, PA 18960 (US). LYONS, Thomas, E. [US/US]; 7850 Locust Valley Road, Quakertown, PA 18951 (US).</b></p>		<p><b>FEILER, Frederic, C., Jr. [US/US]; 925 Tanworth Drive, Raleigh, NC 27615 (US).</b></p> <p>(74) Agents: <b>KITA, Stanley, B. et al.; Howson and Howson, Spring House Corporate Center, P.O. Box 457, Spring House, PA 19477 (US).</b></p> <p>(81) Designated States: <b>CA, JP, MX, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</b></p> <p><b>Published</b>  <i>With international search report.</i></p>
<p>(54) Title: <b>EXTRACORPOREAL PNEUMOPERITONEUM ENCLOSURE AND METHOD OF USE</b></p>		
<p>(57) Abstract</p> <p>Surgical apparatus for providing extra-corporal pneumoperitoneum. One embodiment provides a reversely-turned fluid and gas impermeable fingerless sleeve (14) with a quick connect and disconnect assembly around the cuff of the sleeve (14) for sealing around an abdominal incision to allow hand-assisted minimally invasive surgery under conditions of pneumoperitoneum. A dome-shaped enclosure (62) is provided for use with the quick connect and disconnect assembly to seal around an abdominal incision and maintain pneumoperitoneum during interruptions in a surgical procedure. Another embodiment incorporates a fingerless sleeve (14) which is adhesively secured directly to a patient's skin around an incision. The sleeve is applied over a pre-gloved surgeon's hand, and an outer surgical glove (18) is applied over the sleeve (14) in the region where the fingers and thumb protrude before the sleeve (14) is reversely turned on itself for connection to a patient.</p>		

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EXTRACORPOREAL PNEUMOPERITONEUM ENCLOSURE  
AND METHOD OF USE

Field of the Invention

5       The present invention relates generally to an  
apparatus and method suitable for maintaining  
extracorporeal pneumoperitoneum at an abdominal  
fenestration during surgery, and more particularly to a  
quick connect and disconnect enclosure and method for  
10       insertion of instruments or a surgeon's hand into the  
body cavity through a fenestration for access to organs  
and instruments within the cavity without loss of  
insufflation pressure.

Background of the Invention

15       Laparoscopy and endoscopy have become a preferred  
surgical procedure because it is minimally invasive of  
the patient's body and, in many instances, can be  
performed in short-procedure facilities with minimal  
trauma and significantly reduced recuperation time. In  
20       some cases, a new procedure referred to as hand-assisted  
laparoscopy, or endoscopy, has been employed in which a  
small muscle splitting incision is made just large enough  
for admitting the surgeon's hand into the abdominal  
cavity to enable palpation of organs and manipulation of  
25       surgical instruments, and to provide bio-physical  
feedback. Visual feedback is usually provided as well  
through an endoscope and TV monitor.

      Several medical devices have been developed which  
make it possible for hand-assisted laparoscopy to be  
30       carried out in the abdominal cavity while under  
conditions of pneumoperitoneum. One device, for  
instance, by Patrick F. Leahy et al. disclosed in U.S.  
Patent Application S.N. 08/300,346 filed March 29, 1995  
(International Application PCT/US95/04202 published  
35       October 29, 1995) provides a gas-tight sleeve which  
communicates with the abdominal cavity through an

incision allowing the surgeon's hand access through entry and exit openings at opposite ends of the sleeve. The exit opening is sealed around the incision by a flange adhesively attached to the external surface of the abdomen. After the hand is passed through the entry opening, the sleeve is sealed around the surgeon's forearm by an adjustable cuff. A duckbill check valve disposed between the entry and exit openings forms with the exit opening a substantially gas-tight chamber which allows the surgeon to withdraw his hand from the insufflated cavity with only a slight drop in gas pressure which can be quickly restored.

Another device disclosed in U.S. Patent 5,480,410 to Cuschieri et al. provides a gas-tight enclosure in which a resilient ring at an exit opening is squeezed by hand into an oblong shape for insertion through the abdominal incision, then allowed to expand to its original shape under the edge of the incision to seal the peritoneum and enclosure for sufflation. At least one entry opening is provided for passing an instrument or a surgeon's hand into the enclosure. The enclosure may also include a surgical glove integrally sealed to the entry opening in a glove-box manner for allowing the surgeon's hand sterile access through the exit opening to organs and instruments within the abdominal cavity.

None of these devices, however, satisfies the need for such a gas-tight enclosure which can be quickly disconnected and reconnected as often as necessary during hand-assisted laparoscopic or endoscopic surgery while the enclosure remains sealed in place around the surgeon's hand, and which can maintain abdominal pneumoperitoneum during extended interruptions in an operation for other medical procedures.

Objects of the Invention

Accordingly, it is an object of the present invention to provide a gas-tight extracorporeal pneumoperitoneum enclosure which is worn by the surgeon during hand-assisted laparoscopic or endoscopic surgery, which can be quickly disconnected from a patient as often as necessary in the course of an operation and reconnected while still sealed around the surgeon's hand, which allows the surgeon to manipulate or palpate organs and instruments from within the abdominal cavity, and which provides bio-physical feedback from the surgeon's hand under conditions of pneumoperitoneum.

Another object of the invention is to provide a surgical apparatus which can be continuously sealed around the surgeon's hand and forearm and selectively connected around an open wound while maintaining pneumoperitoneum in the course of a hand-assisted laparoscopic or endoscopic operation, and which will maintain pneumoperitoneum within the body cavity during any interruptions for any other medical procedure in the course of an operation.

A still further object of the invention is to enable minimally invasive surgery with minimal risk of damage to the immune system, and with shorter healing time and less time needed for recuperation in a hospital.

A further object is to provide a disposable surgical device which is relatively simple in design and easy to use.

Summary of the Invention

More specifically, in one embodiment, the extracorporeal pneumoperitoneum enclosure is a fluid and gas impermeable elongate fingerless sleeve having an open proximal end and a distal end with holes arranged to seal gas-tightly around the base of the surgeon's thumb and

each of the fingers. The sleeve section intermediate its ends is reversely-turned on itself before its proximal end is fastened either directly, or indirectly, onto a patient's skin around an incision. Preferably, a quick connect and disconnect assembly at the proximal end of the sleeve gas-tightly seals to the skin around an incision allowing the surgeon to interrupt and resume a hand-assisted laparoscopic surgical procedure under conditions of pneumoperitoneum as often as needed without removing the sleeve from his/her hand. Integral with the quick connect and disconnect assembly is a pressure relief valve for preventing over-sufflation. At least one instrument port is provided in the cuff for admitting, without loss of gas pressure, surgical instruments.

In another embodiment of the extracorporeal pneumoperitoneum enclosure, a fluid and gas impermeable hemispheric envelope is sealed gas-tightly around the incision. A quick connect and disconnect assembly with integral pressure relief valve is secured around an open base for maintaining the abdominal cavity sufflated during interruptions in an operation. This embodiment also includes a sealable instrument port.

Upper and lower seal rings in both embodiments of the quick connect and disconnect assembly have respectively mating interfaces enabling the sleeve and envelope to be interchangeable without removing the lower seal ring previously attached to a patient.

The method for using the apparatus in a hand-assisted laparoscopic operation is as follows. A lower seal ring of the quick connect and disconnect assembly is adhesively sealed to the skin of the patient around the site where a small muscle-splitting incision is made through the abdomen wall and peritoneum. A wound liner and retractor may be inserted into the incision.

protect the wound from contamination and to spread it apart for easier access. Wearing an inner surgical glove, the surgeon inserts his/her hand into the fingerless sleeve until the fingers extend completely through the holes and become tightly sealed around their bases. For extra precaution against leakage, an outer surgical glove is then placed over both the inner glove and the fingerless sleeve. The sleeve is then reversely turned on itself. An upper seal ring of the quick connect and disconnect assembly around the cuff of the glove is then sealingly interconnected with the lower seal ring and the abdomen and glove insufflated to the desired pressure either through a separate cannula or a port in the glove. The surgeon's hand may then be inserted into the abdominal cavity and removed as often as necessary during a laparoscopic procedure. The port in the sleeve permits instruments to be inserted as often as needed. Any increase in sufflating gas pressure, caused by a sudden reduction in volume when inserting the hand, is prevented by the pressure relief valve in the quick connect and disconnect assembly.

Whenever the surgeon wishes to interrupt a surgical procedure while still maintaining pneumoperitoneum, the sleeve is disconnected from the lower seal ring, and in its place the dome-like envelope with upper seal ring are connected to the lower seal ring left on the abdomen and sufflation restored.

Other objects, advantages and novel features of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a view in elevation and partial cross section of an extracorporeal pneumoperitoneum enclosure, or sleeve, according to one embodiment of the invention as applied in hand-assisted laparoscopic surgery in the abdomen;

FIG. 2 is perspective view of various components of the sleeve, or enclosure, of FIG. 1 spatially arranged in order of assembly;

FIG. 3 is a more detailed view, partially in cross section, of a segment of a connect and disconnect assembly shown connected in the enclosure of FIG. 1;

FIG. 4 is a cross sectional view like FIG. 3 but with the assembly shown partially disconnected;

FIG. 5 is a view in cross section of an upper seal ring of the sleeve, or enclosure, taken along the line 5-5 of FIG. 2;

FIG. 6 is a plan view of a lower seal ring with an integral relief valve;

FIG. 7 is a view in cross section of an instrument port shown in the enclosure of FIG. 1; FIG. 8 is a view of the instrument port of FIG. 7 view from within the enclosure of FIG. 1;

FIG. 9 is a view in elevation and partial cross section of an extracorporeal pneumoperitoneum enclosure according to another embodiment of the invention as applied during an interruption of a surgical procedure;

FIG. 10 is a perspective view of an enclosure, or sleeve, similar to the embodiment of FIG. 1, but utilizing a simplified connect and disconnect assembly; and

FIG. 11 is a partially-sectioned elevational view showing the enclosure, or sleeve, of FIG. 10 reversely turned and in use in an operating position.



Detailed Description

Referring now to the drawings, FIG. 1 illustrates an extracorporeal pneumoperitoneum enclosure 10 according to the invention applied to a patient's anterior abdominal wall W. A surgeon's hand extends into the abdominal cavity through a small muscle splitting incision which is protected from wound contamination by a wound protector/retractor 12 such as disclosed in U.S. Patent 5,524,644 to Berwyn M. Crook.

10 In one preferred embodiment, enclosure 10 includes an elongate gas impermeable flexible sleeve 14 of sufficient length to receive the hand and forearm of the surgeon. Sleeve 14 has an intermediate section that extends from a proximal end cuff section 14a to a  
15 "fingerless," distal, hand section 14b where it terminates with holes 15 positioned to receive the full length of the surgeon's thumb and fingers and to seal the sleeve snugly around the root of each as shown in FIG. 2.

As best seen in FIG. 2, sleeve 14 has an inner side 14c which faces outward in FIG. 1 because, in use, the intermediate cuff section is inverted, or reversely-turned on itself, so that the inside faces out. An inner surgical glove 16, worn in direct contact with the hand, is contiguous with inner side 14c, and an outer surgical  
25 glove 18, worn to ensure against leakage at holes 15, covers an outer side 14d. Thus, the distal end portion 14b of the sleeve 14 is sandwiched between the inner and outer surgical gloves 16 and 18, respectively and thereby secured in place.

30 Sleeve 14 is made of surgical grade supple transparent material in one size designed to seal around the fingers of a small hand but which will also stretch slightly under plastic deformation with residual elasticity to accommodate larger hands without  
35 constricting circulation to the fingers. A suitable

material is 2 mil thick polyethylene film such as X-2000 by Pierson Industries. The preferred diameters of the holes 15, in inches, are as follows:

thumb 0.98, index finger 0.79, middle finger 0.87, ring  
5 finger 0.75 and pinky 0.63.

In the embodiments of FIGs. 1-9, an annular quick connect and disconnect coupling means assembly 20 is permanently sealed around the proximal end of cuff section 14a and removably sealed with an adhesive 22 to  
10 the abdominal skin around the protector/retractor 12. Referring to FIGs. 3-6, coupling assembly 20 includes interconnecting upper and lower seal rings 20a and 20b, preferably molded of a medical grade flexible, slightly resilient thermoplastic rubber of Shore 80A hardness such  
15 as Santoprene® made by Advanced Elastomer Systems. Upper ring 20a defines an annular collar 24 permanently sealed around the periphery of cuff section 14a with an upwardly facing annular bead 26 concentrically disposed around collar 24.

20 Lower ring 20b includes an annular flange 28 having adhesive 22 for securing ring 20b to the skin of a patient during surgery. A peel strip 30 (FIG. 2) covers the adhesive until the ring is to be applied to the skin of the abdomen. A preferred adhesive is IT8-59-A by  
25 Tolas Health Care Packaging of Feasterville, Pennsylvania. An annular member 32 sealed around its bottom to flange 28 extends upward and terminates in a downwardly facing annular groove 33 formed to interface in a tight seal with bead 26 of upper ring 20a. An  
30 annular detent 34 extending radially from bead 26 snaps into an annular groove 36 on the inner surface of member 32 when bead 26 and groove 33 are positively engaged as shown in FIG. 3. Pull tabs 38 extending inward from cylinder 24 enable the surgeon's fingers to pull detent

34 inward and disengage it from groove 36, thereby releasing upper ring 16a from lower ring 20b as shown in FIG. 4.

Lower ring 20b further includes a normally closed  
5 gas pressure relief valve 40 for limiting increases in pressure in the abdominal cavity as may be caused when the surgeon inserts his/her hand and displaces the sleeve 14. The valve 40 comprises a seat 42 integrally molded in the periphery of lower ring 20b, a cap 44, a poppet  
10 valve 46, and a helical spring 48. Cap 44 is secured to ring 16b by turning it about its cylindrical axis until tabs 43a on the bottom edge mate with slots 43b around seat 42. An aperture 44a in the top of cap 44 guides a stem 46a of plunger 46 onto seat 42 as well as serves as  
15 a vent for sufflation gas released through valve 40. Spring 48, around stem 46a between the top of cap 44 and a head 46b of plunger 46, biases valve 40 to a normally closed position. A recess 43 in the surface beneath seat 42b forms a channel 47 with flange 28 for continuously  
20 communicating between valve 40 and the abdominal cavity when lower seal ring 20b is adhered to the surface of the abdomen. If the cavity pressure exceeds a safe limit for pneumoperitoneum, e.g. 30 mm Hg, plunger 46 lifts off of seal 42 against the force of spring 48 to release the gas  
25 to ambient atmosphere. The materials of construction for cap 44 and plunger 46 are preferably a rigid thermoplastic polycarbonate of Shore 80C hardness.

FIGs. 10 and 11 illustrate a simplified annular  
assembly means 70 for securing sleeve 14 directly to a  
30 patient. The assembly 70 includes a annular flange 72 of flexible plastic permanently heat-sealed or bonded around the proximal end of sleeve cuff section 14a. An adhesive 74 is coated on the bottom side of flange 72 for applying either directly to the patient's skin, or to a surgical  
35 drape, around the site of the incision. Complementary

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peelable strips 76 around respective halves of the flange cover the adhesive until the glove is ready for attachment to the skin or drape. A boss, that may mount either a pressure relief valve 40, as previously discussed, or provide a sealed instrument port 50, as will be discussed, may be provided in the sleeve 14 adjacent its proximal end as shown in FIG. 10. A preferred material for flange 72 is a 4 mil plastic laminate of EVA/Surlyn®/EA, and a preferred adhesive is IT8-59-A supra.

Sleeve 14 includes an instrument port 50 located close to the proximal end of cuff section 14a to provide an optional entry into the abdominal cavity for instruments such as graspers, staplers, clip applicators, scopes, etc. Referring to FIGs. 7 and 8, port 50 includes a generally cylindrical housing 52 with a flanged base 52a at one end secured to the inner side 14a of cuff section 14b. The other end defines a cone-shaped wall 52b tapering along its conical axis into the housing to a circular hole 54 at the small end which is sized for slidably receiving an instrument without leakage. A duckbill check valve 56 prevents pressure loss when no instrument is present in port 50. It comprises a flanged base 56a at one end secured to the inside of the housing 52 adjacent to wall 52b. The other end tapers to a normally closed slit 56b spaced below hole 54 in a plane transverse to the conical axis of wall 50b. Housing 50 and insert 52 have sufficient resilience for wall 50b to form a gas-tight seal around the instrument's surface and to ensure that slit 56a closes tightly after the instrument is withdrawn. A suitable material found for this purpose is a molded thermoplastic rubber such as Santoprene® by Advanced Elastomer Systems.

FIG. 9 illustrates an alternate embodiment of an extended pneumoperitoneum enclosure 60 according to the

invention for use in place of the glove enclosure 10 during interruptions in surgery conducted under pneumoperitoneum conditions. It comprises a hemispheric dome-shaped envelope 62 of thin transparent flexible polyethylene film and an upper seal ring 64 of like construction as upper seal ring 20a. The perimeter at the open base is sealed around upper seal ring 64 and interconnects with lower seal ring 20b of assembly 20. Of course, enclosure 60 may also include its own lower seal ring such as utilized in the FIGs. 10 and 11 embodiment. Access by surgical instruments is provided by an instrument port 66, like port 50, secured to envelope 62.

A method according to the invention for performing hand-assisted abdominal laparoscopic surgery utilizing the extended pneumoperitoneum enclosures as above-described will now be described.

The site for making the incision is precisely traced on the abdomen of the patient. In the embodiment of FIGs. 1-8, seal ring 20b and sleeve 14 are preferably separated from upper seal ring 20a and placed on the surgeon's hand before ring 20a is attached to the abdomen in order to afford a more clear unobstructed view of the tracing. Peel strip 30 covering adhesive 22 on lower ring 20b is removed and the ring adhered to the abdomen around the tracing.

Guided by the tracing, a small muscle-splitting incision is made through the abdomen wall sufficient in size to allow the surgeon's hand to pass through. The peritoneum is incised roughly the same amount. Wound liner and retractor 12 is installed in the incision to protect the wound from contamination and to spread it apart for easier access by the hand. The abdomen wall

and peritoneum may also be punctured at other locations for receiving an insufflator, a laparoscope and other instruments.

Wearing an inner surgical glove 16, the surgeon dons sleeve 14 by placing his/her hand into fingerless hand section 14b until the thumb and fingers extend completely through holes 15 and become snugly sealed thereby. Cuff section 14a and upper ring 20a (or assembly 70 of FIG. 10) are drawn up over the forearm exposing the outer side 14d of fingerless section 14a. For added protection against leakage around holes 15, an outer surgical glove 18 is preferably placed over the exposed finger portions of inner glove 16 and hand section 14a. If preferred, the surgeon may don the sleeve 14 and attach it to the lower ring 20b before incising the abdomen.

The sleeve 14 is then reversely turned on itself with the cuff section 14a inverted and upper ring 20a is sealed in lower ring 16b by pressing bead 26 into recess 33 until detent 36 of upper ring 20a snaps into groove 36 of lower ring 20b. The abdominal cavity and the annular envelope formed by sleeve 14 may now be insufflated to the desired pressure either through a separate cannula or through port 50 in sleeve 14. The thus-covered surgeon's hand may thereafter enter and re-enter the abdominal cavity as often as necessary during the surgery without losing pneumoperitoneum. Any increase in insufflating gas pressure, such as caused by a reduction in volume inside the sleeve-formed chamber surrounding the surgeon's forearm when inserting the hand, is relieved by pressure relief valve 40.

Should an extended interruption in a surgical procedure be needed while still maintaining pneumoperitoneum, sleeve 14, attached to upper seal ring 20a, may be disconnected leaving in place lower seal ring 20b. Dome-shaped envelope 62, attached to upper seal

ring 64, may then be connected to lower seal ring 20b and insufflation restored.

Of course, when using the embodiment of FIGs. 10 and 11, the surgeon would don the sleeve 14, as described  
5 above, peel strips 76 from the adhesive 74 and place the flange directly on the skin or surgical drape around the incision site after the wound liner and retractor 12 has been installed.

Some of the many advantages and novel features of  
10 the invention should now be readily apparent. For example, an extracorporeal pneumoperitoneum enclosure is provided which can be continually worn by the surgeon during hand-assisted laparoscopic surgery under conditions of pneumoperitoneum without loss of free hand  
15 and finger movement. It allows the surgeon to quickly disconnect and reconnect the enclosure from the patient while still retaining it on his/her hand. An alternate embodiment provides a dome-like enclosure which can be substituted for the sleeve whenever a protracted  
20 interruption in a surgical procedure is necessary. It enables minimal invasive surgery and risk of damage to a patient's immune system. Due to the smaller incisions, shorter healing time and less time for recuperation in the hospital is possible. The enclosures are also  
25 relatively simple in design and easy to use.

It will be understood, of course, that various changes in the details, materials, steps and arrangement of parts which have been herein described and illustrated in order to explain the nature of the invention may be  
30 made by those skilled in the art within the principle and scope of the invention as expressed in the appended claims.

## Claims:

1. Apparatus for use in providing extracorporeal pneumoperitoneum around a surgical incision in a patient, comprising:

an elongate flexible sleeve (14) having a distal end portion (14b) for covering a surgeon's hand, an intermediate portion for covering the surgeon's forearm, and a proximal portion (14a) having an end opening enabling insertion of the surgeon's hand and forearm, and

means for releasably gas-tightly securing said proximal portion (14a) end opening to the patient around the surgical incision and enabling said intermediate portion to be reversely turned to extend along the surgeon's forearm when said sleeve (14) is operatively secured to the patient and insufflated.

2. Apparatus according to claim 1 wherein said distal portion (14b) of said flexible sleeve (14) has a plurality of openings (15) for receiving a surgeon's fingers and thumb.

3. Apparatus according to claim 2 wherein said sleeve (14) is formed of supple plastic which conforms, but does not continuously constrict, about the bases of the fingers and thumb when the envelope is installed and the surgeon's hand clasped.

4. Apparatus according to claim 3 wherein said plastic material is a polyethylene film.

5. Apparatus according to claim 2 wherein the diameters of said openings (15), in inches, are as follows: thumb 0.98, index finger 0.79, middle finger 0.87, ring finger 0.75 and pinky 0.63.



6. Apparatus according to claim 1 wherein said proximal end gastight sealing means (20) includes ring means connected to said sleeve (14) and adapted to be adhesively secured to the patient around the incision.

7. Apparatus according to claim 6 wherein said ring means includes an annular base (20b) adhesively secured to the patient and an annular ring (20a) releasably engageable with said base (20b).

8. Apparatus according to claim 7 wherein said annular ring (20a) matingly engages interiorly of said base (20b) in gastight relation therewith.

9. Apparatus according to claim 7 including a pressure relief valve (40) carried by said annular base (20b) for relieving overpressures above about 30 mm Hg.

10. Apparatus according to claim 7 including a closure (60) having an annular ring (64) releasably engageable with said base (20b) affording selective sealed connection thereto of either said sleeve (14) or said closure (60).

11. Apparatus according to claim 10 wherein said closure (60) includes a flexible hemispheric dome (62) overlying said base ring (20b).

12. Apparatus according to claim 11 wherein said closure (60) includes a port (66) having an interiorly-opening duckbill check valve (56) affording passage of a surgical instrument into the closure (60).

16

13. Apparatus according to claim 2 including an outer surgical glove (18) applied on said surgeon's hand after being operatively inserted into said distal portion (14b) of said sleeve and through said openings (15) for ensuring sealed closure of said openings (15).

14. Apparatus according to claim 13 including an inner surgical glove (16) disposed on the surgeon's hand inwardly adjacent said sleeve distal portion (14b) for cooperating with said outer surgical glove (18) to sandwich said sleeve distal end (14b) therebetween.

15. Apparatus for preventing over-insufflation of a body cavity during endoscopic surgery utilizing a flexible sleeve (14) having one end portion (14a) operatively sealingly connected to a patient around an incision and another end portion (14b) operatively sealingly connected to a surgeon, the apparatus comprising:

a pressure relief valve (40) having an inlet in gas communication with the interior of said sleeve (14) and having an outlet to ambient atmosphere, and

means for biasing said valve (40) into a closed position normally blocking flow from the inlet to the outlet until a predetermined pressure level is reached within said sleeve (14),

whereby over-insufflation of the body cavity can be avoided during endoscopic surgical movements of the surgeon.

16. Apparatus according to claim 15 wherein said pressure relief valve (40) includes a base (20b) releasably connectable to the patient in proximity with the incision.

17. Apparatus according to claim 16 wherein said base (20b) is formed integral with a ring surrounding said incision and adhesively securable to the patient.

18. Apparatus according to claim 15 wherein said predetermined pressure is less than about 30 mm Hg.

19. Apparatus according to claim 17 including a closure (60) having a self-sealing instrument port (66), said closure (60) being releasably engageable with said ring (20b) for affording selective engagement of either said closure (60) or said sleeve (14) on said ring (20b).

20. Apparatus according to claim 15 wherein said flexible sleeve (14) has an intermediate portion reversely turned on itself to form a variable volume annular chamber around the surgeon's forearm.

21. Apparatus for providing extracorporeal pneumoperitoneum around a surgical incision, comprising:  
a flexible gas impermeable envelope (14) having a proximal section (14a) defining a proximal end opening, a distal section (14b) with holes (15) for receiving a surgeon's digits, and an intermediate section reversely turnable about the surgeon's forearm with the distal section (14b) telescopically moveable into the proximal section (14a); and  
ring means (20) carried by said envelope (14) about said proximal end opening for securing said envelope (14) in sealing contact with skin around the incision.

22. Apparatus according to claim 21 wherein said ring means (20) includes releasably matingly engageable rings (20a, 20b), one mounted on said envelope proximal end and the other adhesively connectable to said skin.

23. Apparatus according to claim 22 including a closure (60) having a ring (64a), like in construction to said one ring, for enabling said closure (60) to be selectively mounted onto said skin adhered ring.

24. Apparatus according to claim 23 including:  
a bead (26) formed in said one ring around said envelope proximal end opening; and  
a groove (33) formed in said other ring for interengaging said bead (26).

25. Apparatus according to claim 24 further comprising:  
detent means (34, 36) formed in said rings for interlocking when said bead (26) and said groove (33) are fully engaged.

26. Apparatus according to claim 21 further comprising:  
pressure relief valve means (40) carried by said ring (20b) for communicating with said envelope (14) to vent insufflated gas when its pressure exceeds a pre-selected limit.

27. Apparatus according to claim 26 wherein said preselected pressure limit is approximately 30 mm Hg.

28. Apparatus according to claim 21 further comprising:  
port means (50) fixed to said sleeve (14) and formed to admit a surgical instrument while maintaining extracorporeal pneumoperitoneum.

29. Apparatus according to claim 28 wherein said port means (50) further includes:  
a generally cylindrical housing (52) having a conical wall (52b) tapering inward to form a circular hole (54) for slidably receiving said surgical instrument;  
a duckbill check valve (56) secured to said housing (52) and having a normally closed slit spaced below said hole (54) in a plane transverse to a conical axis of said wall (52b) for slidably receiving the instrument in series with said hole (54).

30. Apparatus according to claim 29 wherein:  
said housing (52) has sufficient resilience for said hole (54) to form a gas-tight seal around the instruments' surface; and  
said duckbill check valve (56) has sufficient resilience for said slit to close tightly upon itself when the instrument is withdrawn therefrom.

31. Apparatus for hand-assisted minimally invasive surgery under conditions of pneumoperitoneum, comprising:  
a gas impermeable flexible sleeve (14) having a fingerless distal hand section (14b) terminating in holes (15) for receiving the thumb and fingers of a surgeon's hand, an intermediate cuff section extending from said distal hand section (14b), and a proximal end section (14a) terminating in an opening,  
said intermediate cuff section being reversely turnable on itself for extending along the surgeon's forearm when the proximal end opening (14a) is displaced toward the distal end (14b),

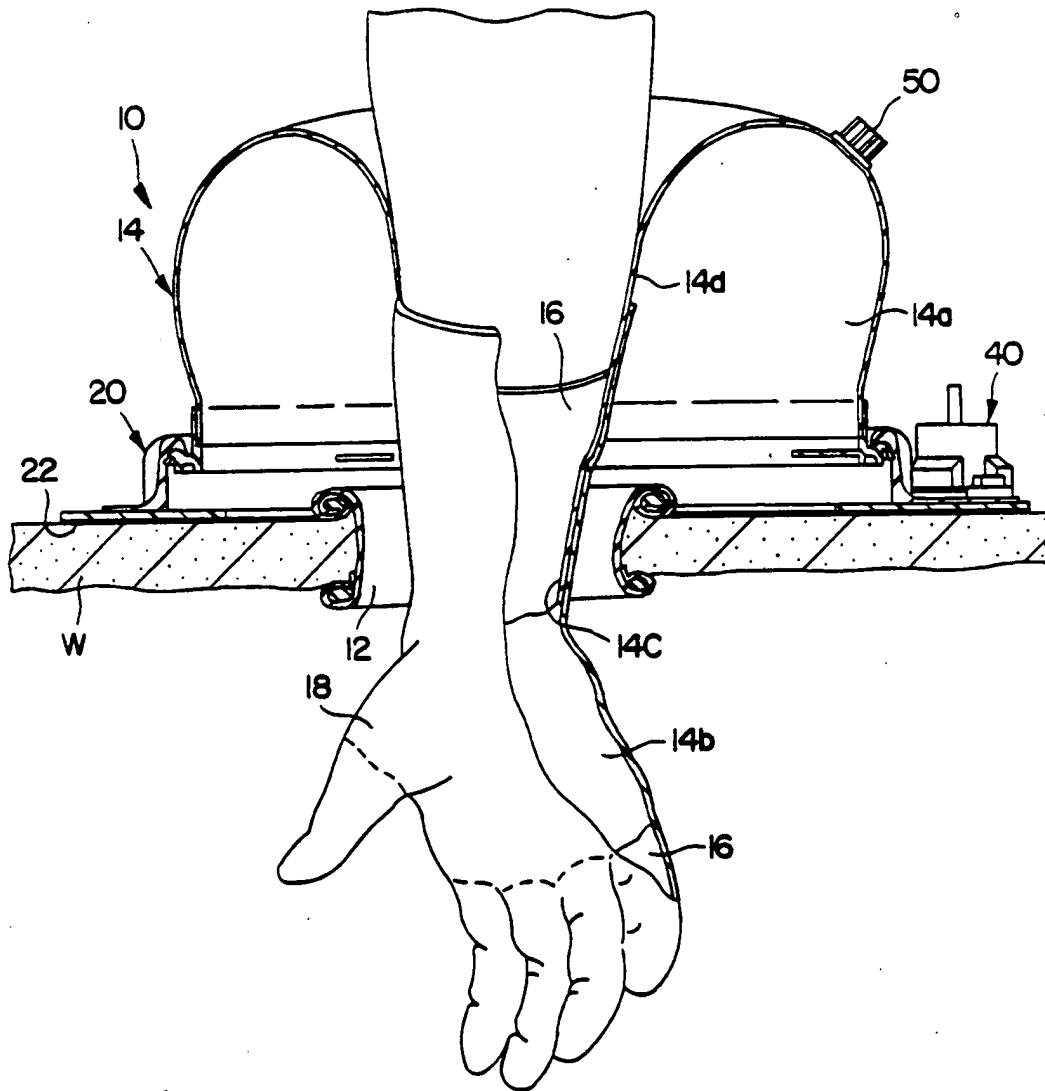
a peelable adhesive ring (20b) carried by said sleeve (14) for sealing contact with skin around an abdominal incision; and means for releasably coupling said adhesive ring (20b) to said sleeve (14) about its proximal end opening.

32. Apparatus according to claim 31 wherein said releasable coupling means includes a first ring (20a) sealed to said sleeve (14) about its proximal end opening for releasably sealingly engaging interiorly of said adhesive ring (20b).

33. Apparatus according to claim 31 including pressure relief valve means (40) carried by said adhesive ring (20b) for relieving pressure above a predetermined level occurring inside said reversely turned sleeve (14).

34. Apparatus according to claim 31 including an outer surgical glove (18) encasing the surgeon's hand after insertion through the distal end holes (15) for effecting a positive seal of the holes (15).

35. Apparatus according to claim 34 including an inner surgical glove (16) encasing the surgeon's hand interiorly of the sleeve (14) for sandwiching the sleeve distal end (14b) between inner and outer surgical gloves (16, 18).



**FIG. 1**

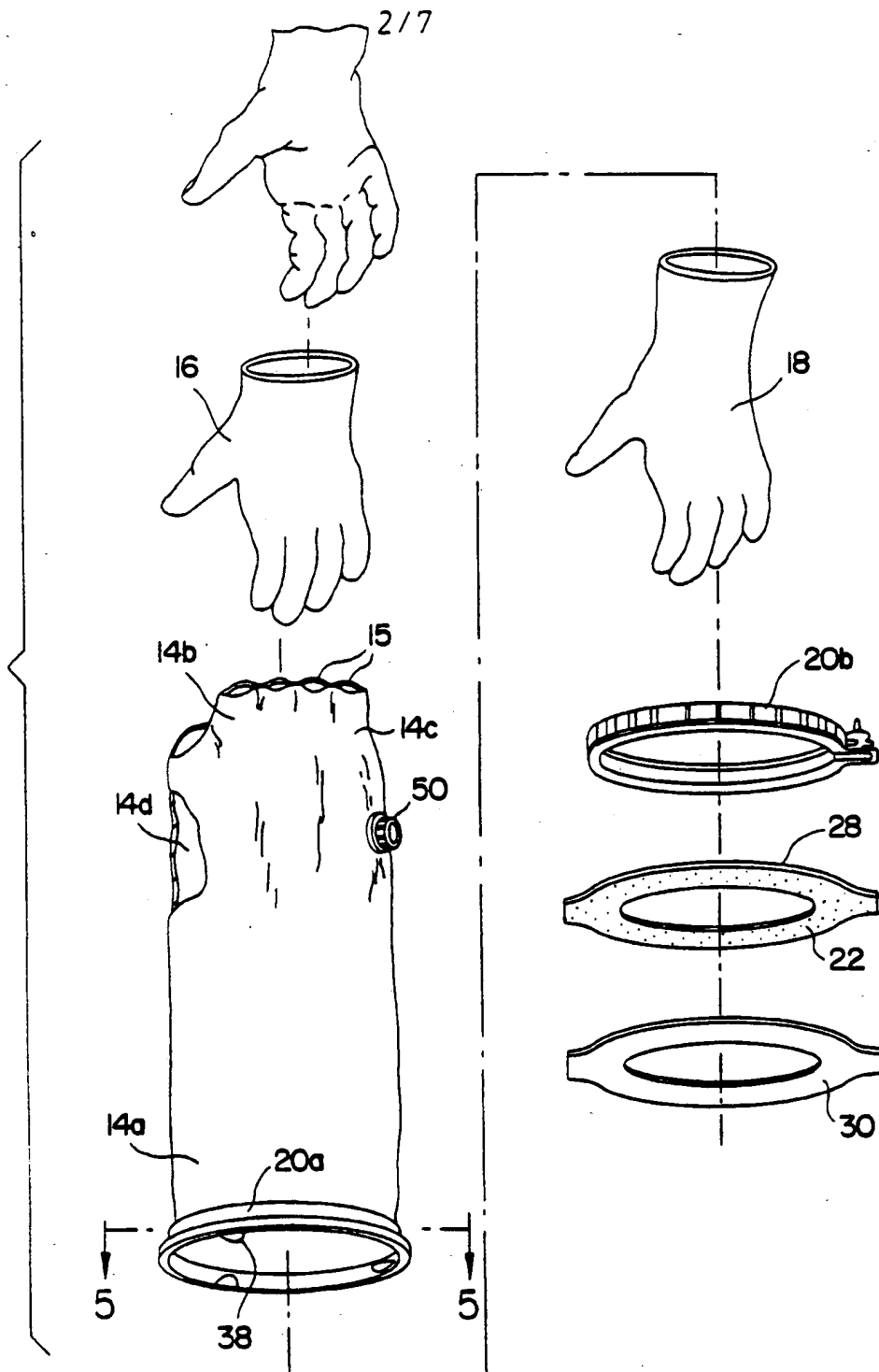


FIG. 2

SUBSTITUTE SHEET (RULE 26)



3/7

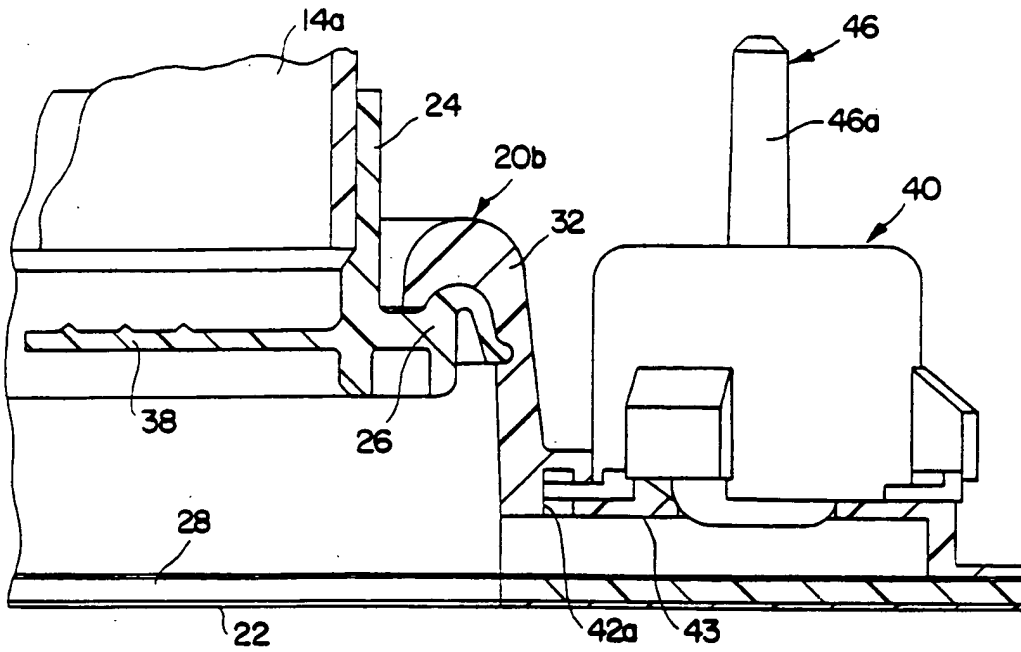


FIG. 3

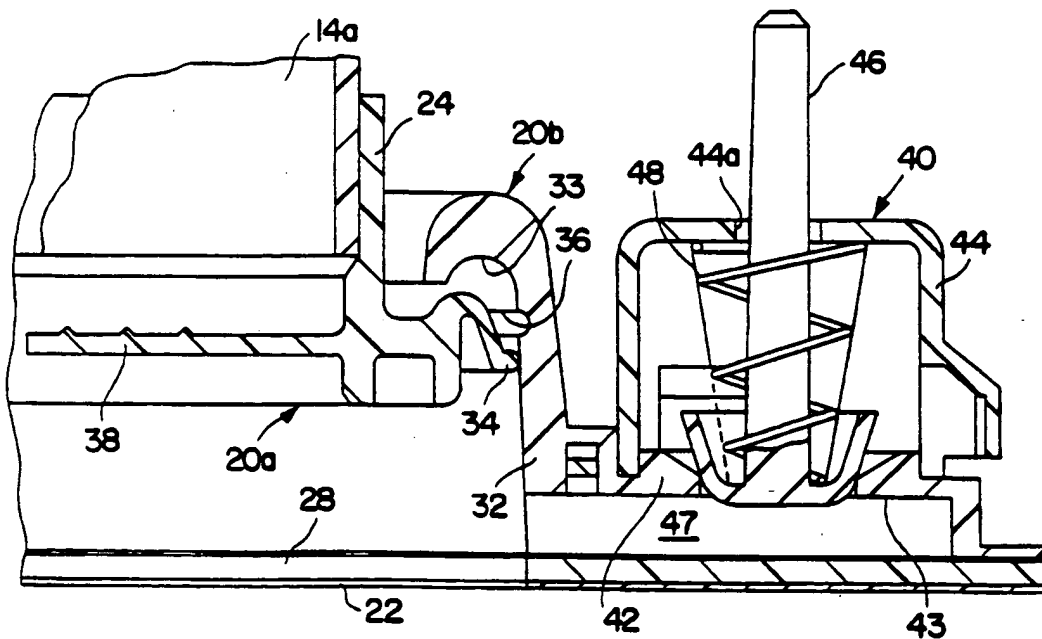
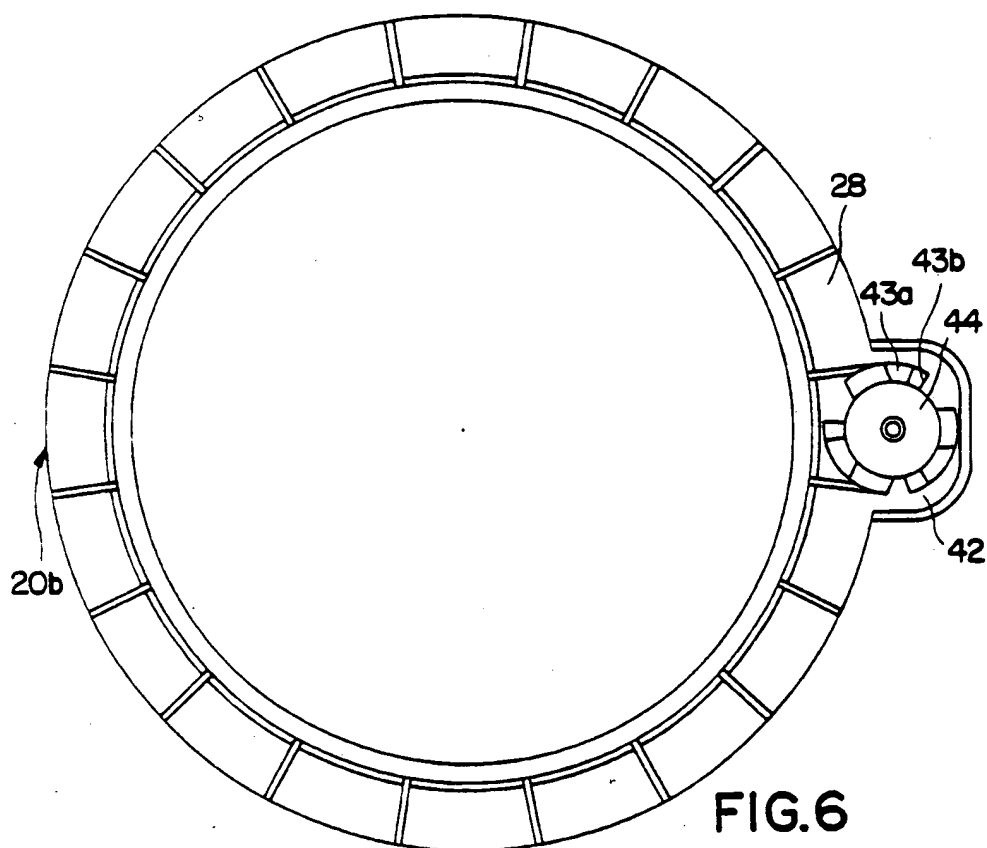
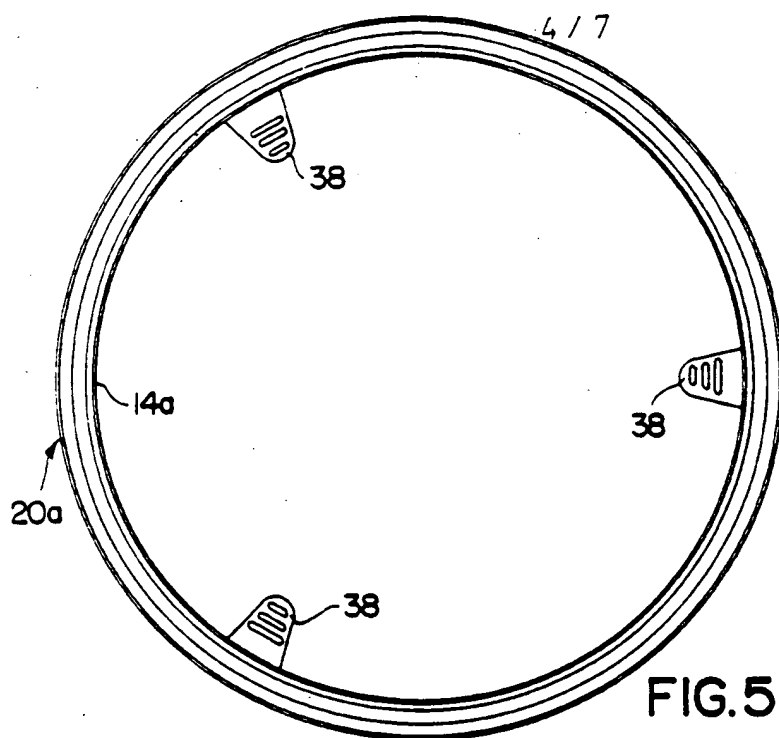


FIG. 4

SUBSTITUTE SHEET (RULE 26)



5 / 7

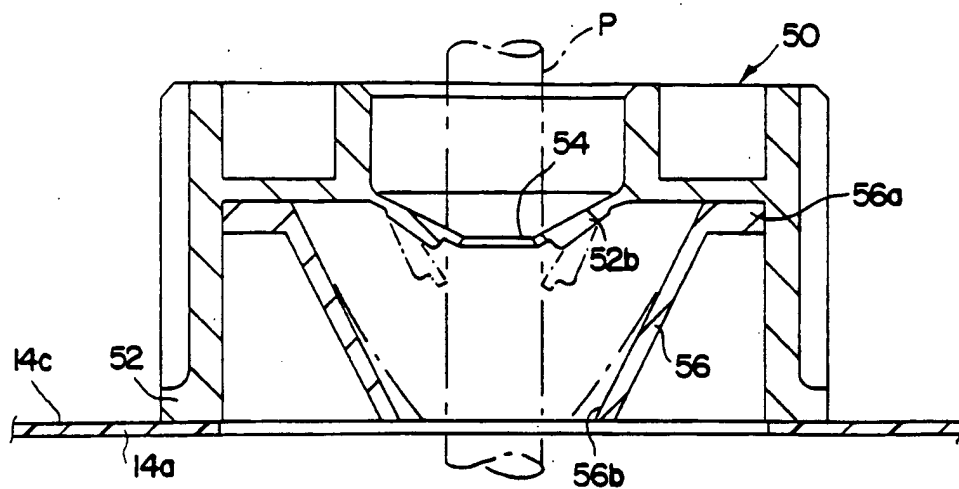


FIG. 7

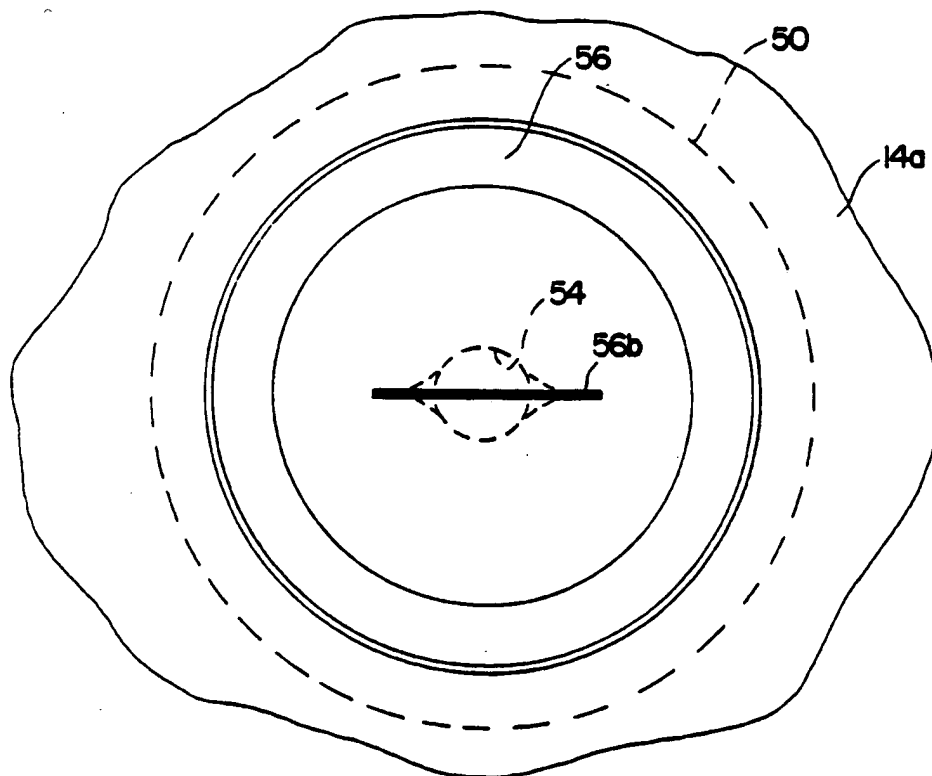


FIG. 8

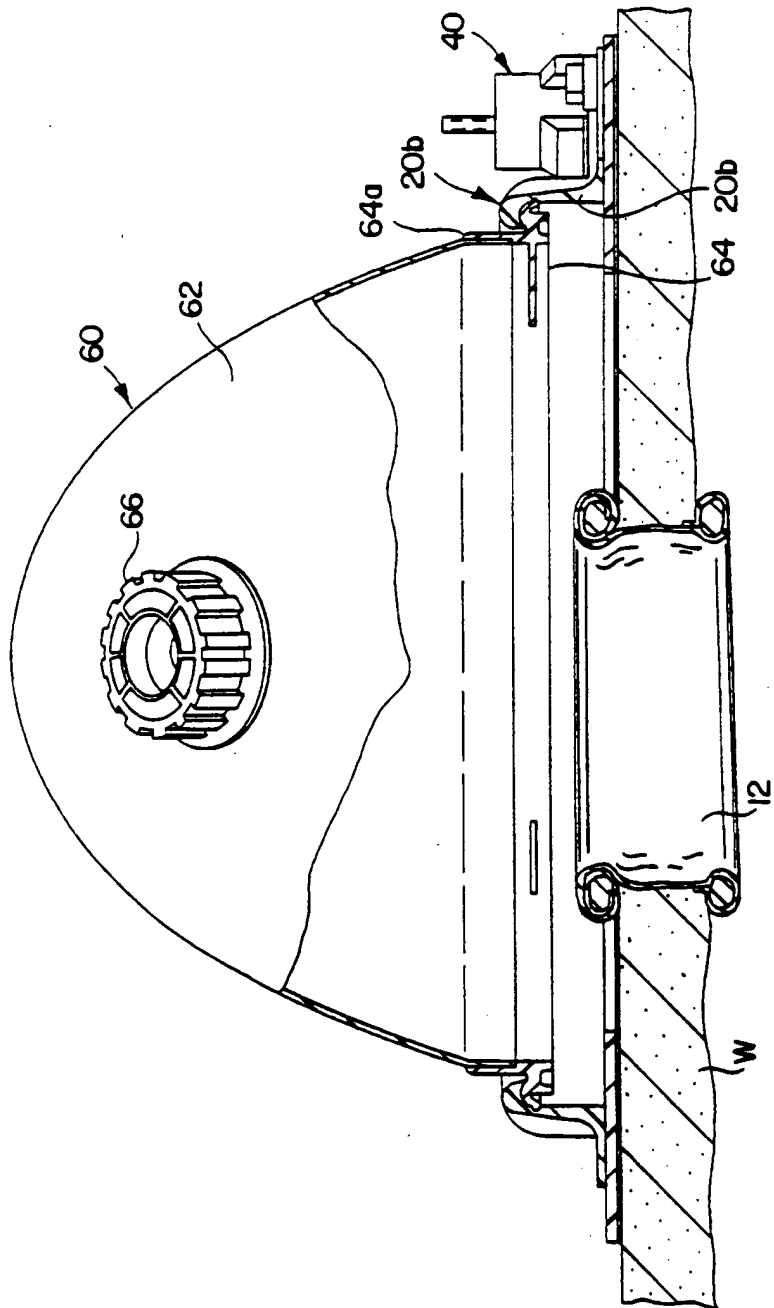
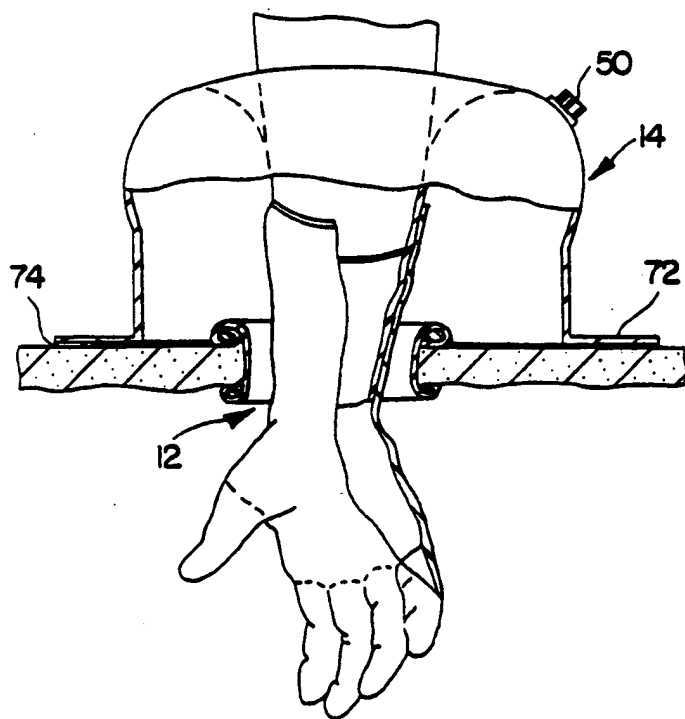
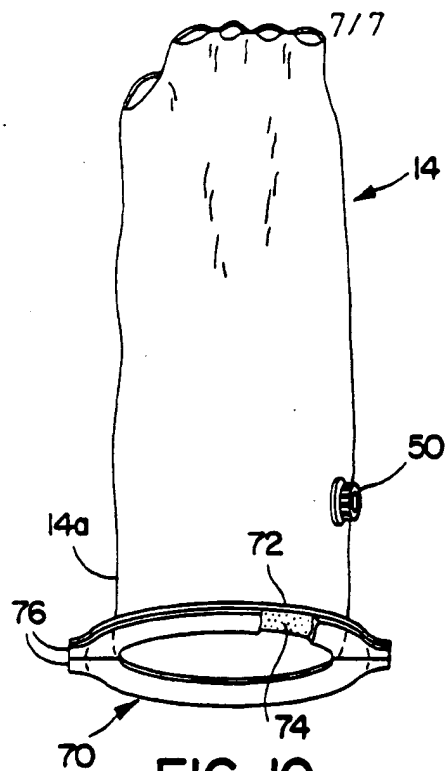


FIG. 9



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/18168

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) : A61B17/00, 17/08; A61D 1/00; A61M 5/32 US CL : 600/207; 604/174; 606/201, 213, 215 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : Please See Extra Sheet. Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X P	US 5,640,977 A (LEAHY et al) 24 June 1997, entire document.	1, 6
X	US 5,522,791 A (LEYVA) 04 June 1996, entire document.	1, 6, 7, 15-18, 20
X	US 5,480,410 A (CUSCHIERI et al) 02 January 1996, entire document.	15-20
A	US 5,082,005 A (KALDANY) 21 January 1992, entire document.	15-20
A	US 5,366,478 A (BRINKERHOFF et al) 22 November 1994, entire document.	15-20
A	US 4,485,490 A (AKERS et al) 04 December 1984, entire document.	1-35
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "B" earlier documents published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "A" document member of the same patent family		
Date of the actual completion of the international search 27 FEBRUARY 1998		Date of mailing of the international search report 10 APR 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer <i>H. Leon Miett</i> RONALD K. STRIGHT, JR. Telephone No. (703) 308-2113

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/18168

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,069,913 A (HARRIGAN) 24 January 1978, Fig. 1.	1-35
A	US 5,370,625 A (SHICHMAN) 06 December 1994, entire document.	1-35

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/18168

## B. FIELDS SEARCHED

Minimum documentation searched

Classification System: U.S.

128/846, 847, 850, 852, 856, 897; 600/21, 201, 203-208, 219-221, 227, 235; 602/60-64; 604/23, 26, 167, 169, 174, 180;  
606/1, 191, 192, 198, 201, 213, 215